Title: IMPLANT FOR DRAINING CHAMBER WATER FROM THE FRONT EYE CHAMBER INTO THE EPISCLERAL VEINS

Inventor(s): Winfried MAYR et al.

Docket. No.: 37966-0074

Appl. No.: 10/542,404

Filing Date: July 15, 2005

- Transmittal Letter Concerning A Filing Under 35 CFR §371 (Form PTO-1390)
- Preliminary Amendment
- Declaration and Power of Attorney
- English Translation of Intl. App. No. PCT/AT2003/000381
- Check in the amount of **$195.00** (Check No. 095706)
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Date Due: N/A
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Respectfully,
HELLER EHRMAN LLP

PTO-1390 (Rev. 02-2005)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
37966-0074	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	
10/542,404	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/AT03/000381	December 23, 2003	January 23, 2003

TITLE OF INVENTION
Implant For Draining Chamber Water From The Front Eye Chamber Into The Episcleral Veins

APPLICANT(S) FOR DO/EO/US
Winfried MAYR; Clemens VASS; Ewald UNGER

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☑ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☑ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☑ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☑ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☑ Other items or information: Declaration and Power of Attorney

PTO-1390 (Rev. 02-2005)
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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/542,404	PCT/AT03/000381	37966-0074

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☐ Basic national fee..... $300	$	
22. ☐ Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... $100 All other situations..... $200	$	
23. ☐ Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... $100 International Search Report prepared and provided to the Office..... $400 All other situations..... $500	$	
TOTAL OF 21, 22 and 23 =	$	
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is $250 for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
- 100 =	/50 =		x $250	$

Surcharge of $130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				$ 130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$
Total claims	9 - 20 =	0	x $ 50	$
Independent claims	1 - 3 =	0	x $200	$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $360	$
			TOTAL OF ABOVE CACULATIONS =	$ 130.00
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.				
			SUBTOTAL =	$ 65.00
Processing fee of $130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$ 130.00
			TOTAL NATIONAL FEE =	$
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property			+	$
			TOTAL FEES ENCLOSED =	$ 195.00
10/28/2005 GFREY1 00000114 10542404			Amount to be refunded:	$
01 FC:2617 65.00 OP 02 FC:1618 130.00 OP			Amount to be charged:	$

a. ☑ A check in the amount of $ 195.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 08-1641 . A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 26633

Date: October 25, 2005

SIGNATURE

John P. Isacson
NAME

33,715
REGISTRATION NUMBER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 37966-0074

Applicant(s)	Winfried MAYR et al.	Confirmation No.: 2964
Appl. No.:	10/542,404	Examiner: Unassigned
Filing Date:	July 15, 2005	Group Art Unit: Unassigned

Title: IMPLANT FOR DRAINING CHAMBER WATER FROM THE FRONT EYE CHAMBER INTO THE EPISCLERAL VEINS

PRELIMINARY AMENDMENT B

Commissioner for Patents
United States Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Prior to examination, please enter the following amendments.

AMENDMENTS

AMENDMENTS TO THE CLAIMS

1. **(Original)** Implant for draining chamber water from the front eye chamber into one or more episcleral veins, consisting of at least one tubular part (1), characterized in that, to drain the chamber water into an episcleral vein, this tubular part (1) is provided with a guide wire (8) stabilizing it and provided with a distal sharp tip in order that, after the piercing of the particular vein and withdrawal of the guide wire, it can be brought with its distal outlet end (3) into the episcleral vein, while the proximal inlet end (2) can be introduced into the front eye chamber.

2. **(Original)** Implant according to claim 1, characterized in that the proximal (4) and the central area (5) contain several tubular parts (1) which branch out in the distal area and can be implanted with their distal ends (3) into a plurality of episcleral veins, these tubular parts (1) containing each a guide wire (8) for piercing the particular episcleral veins (Fig. 5).

3. **(Currently amended)** Implant according to claim 1 ~~or 2~~, characterized in that the open distal end or ends (3) of the tubular part (1) are rounded or beveled so as to be able to introduce them atraumatically into one or more episcleral veins.

4. **(Currently amended)** Implant according to ~~any one of claims~~ claim1 ~~to 3~~, characterized in that the diameters of the lumina forming the tubular parts (1) are between 0.02 mm and 0.1 mm.

5. **(Currently amended)** Implant according to ~~any one of claims~~ claim1 ~~to 4~~, characterized in that the tubular portion (1) is encased at least partially with silicone or other appropriate plastic.

6. **(Currently amended)** Implant according to ~~any one of claims~~ claim1 ~~to 5~~, characterized in that at the tubular portion (1) a plate (6) is applied which can contain one or more eyelets (7) for fixation by stitching.

7. **(Currently amended)** Implant according to ~~one or more of claims~~ claim1 ~~to 6~~, characterized in that at least parts of the implant are made from biocompatible material, for example silicone or other appropriate plastics, from stainless steel, from titanium, from a noble metal such as silver, gold or platinum, or from a biological material.

8. **(Currently amended)** Implant according to ~~any one of claims~~ claim1 ~~to 7~~, characterized in that at least parts of the implant are coated with suitable material to produce a desired biological reaction or to prevent an undesired biological reaction.

9. **(Currently amended)** Implant according to ~~any one of claims~~ claim 1 ~~to 8~~, characterized in that a check valve is provided in the tubular portion (1), by which retrograde flow of blood into the front eye chamber is prevented.

REMARKS

Claims 1-9 are pending in the application. Claims 3-9 are amended to remove multiple dependencies. No new matter has been added. A first office action on the merits is awaited.

Respectfully submitted,

October 25, 2005
Date

John P. Isacson
Reg. No. 33,715

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DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I HEREBY DECLARE:

THAT my residence, post office address, and citizenship are as stated below next to my name;

THAT I believe I am the original, first, and sole inventor (if only one inventor is named below) or an original, first, and joint inventor (if plural inventors are named below or in an attached Declaration) of the subject matter which is claimed and for which a patent is sought on the invention entitled

IMPLANT FOR DRAINING CHAMBER WATER FROM THE FRONT EYE CHAMBER INTO THE EPISCLERAL VEINS

the specification of which (check one)

☐ is attached hereto.

☒ was filed on July 15, 2005 as U.S. Serial No. 10/542,404

THAT I do not know and do not believe that the same invention was ever known or used by others in the United States of America, or was patented or described in any printed publication in any country, before I (we) invented it;

THAT I do not know and do not believe that the same invention was patented or described in any printed publication in any country, or in public use or on sale in the United States of America, for more than one year prior to the filing date of this United States application;

THAT I do not know and do not believe that the same invention was first patented or made the subject of an inventor's certificate that issued in any country foreign to the United States of America before the filing date of this United States application if the foreign application was filed by me (us), or by my (our) legal representatives or assigns, more than twelve months (six months for design patents) prior to the filing date of this United States application;

THAT I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment specifically referred to above;

THAT I believe that the above-identified specification contains a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, and sets forth the best mode contemplated by me of carrying out the invention; and

THAT I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I HEREBY CLAIM foreign priority benefits under Title 35, United States Code §119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate or of

any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number	Country	Foreign Filing Date	Priority Claimed?	Certified Copy Attached?
PCT/AT2003/000381	**WIPO**	**December 23, 2003**	**Yes**	**No**
A 88/2003	**Austria**	**January 23, 2003**	**Yes**	**No**

I HEREBY CLAIM the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

U.S. Provisional Application Number	Filing Date

I HEREBY CLAIM the benefit under Title 35, United States Code, §120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Application Number	Parent Filing Date	Parent Patent Number

I HEREBY APPOINT the following registered attorneys and agents of the law firm of **HELLER EHRMAN LLP** included in the Customer Number provided below:

CUSTOMER NO. 026633

and I request that all correspondence be directed to:

HELLER EHRMAN LLP
1717 Rhode Island Avenue, NW
Washington, DC 20036
Telephone: (202) 912-2000
Facsimile: (202) 912-2020

I UNDERSTAND AND AGREE THAT the foregoing attorneys and agents appointed by me to prosecute this application do not personally represent me or my legal interests, but instead represent the interests of the legal owner(s) of the invention described in this application.

I FURTHER DECLARE THAT all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Name of first inventor	**Winfried MAYR**
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Date	1. September 2005

37966-0074

IMPLANT FOR DRAINING CHAMBER WATER FROM THE FRONT EYE CHAMBER INTO THE EPISCLERAL VEINS

The present invention relates to an implant for draining chamber water from the front eye chamber into the episcleral veins, for use in glaucoma, consisting of the measures listed in the generic part of claim 1.

Glaucoma is a disease which is characterized by chronically progressing lesions in the optic nerve with the chief risk factor of elevated intraocular pressure. Approximately 2 :l of chamber water are produced per minute in the interior of the eye and drain through the trabecular mechanism situated in the front ocular chamber into the canal of Schlemm, and from there through the chamber water veins into the venous system. The main physiological resistance to this chamber water drainage lies in the juxtacanicular portion of the trabecular meshwork, i.e., between the front eye chamber and the canal of Schlemm. In the case of chronic open angle glaucoma, even this resistance is pathologically elevated.

Fistulating glaucoma operations (trabeculectomy) presently represent the standard procedure in operations for lowering ocular pressure in glaucoma patients. The chamber water in that case is drained through a wound in the sclera from the front eye socket under the connective tissue and carried away. While the short-term successes of about 90% are acceptable, in the course of a few years the healing of the wound leads not rarely to closure of the fistula and thus to late failure of the operation.

Another drainage mode for chamber water uses cyclodialysis. In this operation about 3 mm is removed from the limbus of the sclera, the sclera is severed and a spatula is introduced through it between the sclera and the ciliary body beneath it. This spatula is

pushed forward up to the corner of the chamber and thus the front chamber of the eye is opened. Thus a connection between the front chamber and the gap between the ciliary body and sclera (i.e., the supraciliary gap). Although the success rates of this operation are acceptable, the technique has been neglected on account of the very frequent and poorly controllable hypotonia it entails.

New operative techniques of non-penetrative glaucoma surgery (deep sclerectomy, viscocanalostomy) have lately demonstrated that the canal of Schlemm can be repeatably represented in chronic open-angle glaucoma, and furthermore it can also be used functionally at least in viscocanalostomy. In EP 0 898 947 A2 an implant was reported which is implanted in the canal of Schlemm in connection with a viscocanalostomy for permanent extension into the canal of Schlemm. In the deep sclerectomy, a fistulation under the connective tissue is sought, because in some cases the attempt is made to support this by the use of implants. Nevertheless, these methods were unable to solve the problem of postoperative scarring, so that the medium-term success rates are similar to those of trabeculectomy. It is common to all methods for the non-penetrative glaucoma surgery that a thin layer of tissue, also called a trabeculo-descemetic window, remains intact and exercises a not precisely definable and also variable effect on the resistance to drainage (Dietlein TS, Graefe's Arch Ophth 2000).

An improvement of the chamber water drainage from the front chamber into the canal of Schlemm, and simultaneously keeping the canal of Schlemm open, is the purpose also of the apparatus described in WO 00/13627 A1. Here a stent is implanted in the canal of Schlemm, which stretches the trabecular mechanism and has openings directed as the trabecular mechanism.

In complicated cases, e.g., after multiple preliminary operations, drainage implants have long been used (Molteno, Krupin, Schocket, Baerveldt, Ahmed) which are all

constructed on the same principle: a thin tube (usually of silicone) is introduced with its open end into the front eye chamber, drains the water to a plate or cerclage band affixed to the back of the pupil. Around this plate or the cerclage band a capsule eventually forms, while the resistance to flow (and thus the intraocular pressure) is determined by the permeability of this capsule as well as the surface of the capsule. These methods also involve the problem of scarring.

Spiegel describes (1999) in connection with cadaver eyes, a method for draining from the front eye chamber directly into the canal of Schlemm. He used for this purpose a silicon tube with an outside diameter of 0.15 mm and an inside diameter of 0.05 mm.

In International Patent Application WO 00/64393 A1 an implant is described for draining the chamber water from the front eye chamber into the canal of Schlemm. It can be introduced with its open proximal portion into the front eye chamber, on the one hand, and on the other hand with the distal portion into the canal of Schlemm on both sides.

Both in Spiegel's work and in the international patent cited above, the problem of the stable fixation of the drainage implant remains unsolved. A solution for this has been given in Patent WO 02/087479 A2.

For the majority of eyes suffering from glaucoma, the direct implantation of a drainage implant into the canal of Schlemm appears to be a usable method. While this might offer the advantage of a physiological drainage way, such a solution cannot be considered in some patients. Above all in the case of pre-operated eyes, but also in many forms of glaucoma, as for example in the case of pseudo exfoliation glaucoma, the canal of Schlemm might be partially obliterated, or at least impaired in its operation (Ritch R. Surv Opthalmol 2001; 45:165). In these cases a direct drainage into the episcleral veins might be helpful.

It is the object of the present invention to create an implant for the drainage of chamber water from the front eye chamber into the episcleral veins.

To solve this problem the implant of the invention has the features set forth in the specific part of claim 1.

The invention is described hereinafter by exemplification without limiting the general idea of the invention, by means of embodiments with reference to the drawings, wherein:

Figure 1 shows a schematic representation of a top plan view of a drainage implant corresponding in part to the present invention;

Figure 2 shows a schematic representation of a side view of a drainage implant corresponding in part to the present invention;

Figure 3 shows a schematic representation showing a detail view of the distal end of a drainage implant corresponding partially to the present invention;

Figure 4 shows a schematic representation showing a drainage implant corresponding partially to the present invention after removal of the guide wire; and

Figure 5 shows a schematic representation showing a drainage implant corresponding partially to the present invention, in an embodiment with two tubular parts.

In what follows, a preferred variant of the invention is explained in detail. The present invention is directed to an implant for the drainage of chamber water from the front eye

chamber into the episcleral veins.

Figures 1- 4 show an embodiment of the present invention of the implant with a tubular portion 1 which has at least one lumen and can be introduced with its open proximal end 2 for drainage of the chamber water into the front eye chamber, and can be introduced with its open distal end 3 into an episcleral vein. In the proximal area 4 and in the center area 5 of the implant, the tube 1 is jacketed in plastic, this jacketing being formed in the center area 5 as a plate 6 with eyelets 7 to permit the stabilization and fixation of the implant by means of sutures.

For the implantation of the tube 1 into an episcleral vein, the implant contains inside of the tube 1 a guide wire 8 with a sharp front end, which on the one hand stabilizes the very thin tube 1 and with which secondly the vein is pierced.

In operation, the conjunctiva is opened, an episcleral vein is uncovered and pierced with the tip of the guide wire 8. After the punctio the tube 1 is pushed forward with its distal end 3 into the vein and then affixed with the eyelets to the sclera with sutures. Then the guide wire 8 is removed and the proximal end 2 of the implant is introduced through a limbic puncture incision of suitable diameter into the front chamber of the eye. The proximal area 4 and the central area 5 of the implant can be shifted under a scleral flap.

Figure 5 shows an embodiment in which the proximal area 4 and the central area 5 of the implant are in the form of double-lumen tubes. These branch at the distal end 3 into two separate tubes 1 which can be introduced each into an episcleral vein. In the proximal area 4 and in the central area 5 the double tube is encased in plastic, and in the middle area this casing is in the form of a plate 6 with the eyelets 7 in order to permit the implant to be stabilized and affixed with stitches.

Claims

1. Implant for draining chamber water from the front eye chamber into one or more episcleral veins, consisting of at least one tubular part (1), characterized in that, to drain the chamber water into an episcleral vein, this tubular part (1) is provided with a guide wire (8) stabilizing it and provided with a distal sharp tip in order that, after the piercing of the particular vein and withdrawal of the guide wire, it can be brought with its distal outlet end (3) into the episcleral vein, while the proximal inlet end (2) can be introduced into the front eye chamber.

2. Implant according to claim 1, characterized in that the proximal (4) and the central area (5) contain several tubular parts (1) which branch out in the distal area and can be implanted with their distal ends (3) into a plurality of episcleral veins, these tubular parts (1) containing each a guide wire (8) for piercing the particular episcleral veins (Fig. 5).

3. Implant according to claim 1 or 2, characterized in that the open distal end or ends (3) of the tubular part (1) are rounded or beveled so as to be able to introduce them atraumatically into one or more episcleral veins.

4. Implant according to any one of claims 1 to 3, characterized in that the diameters of the lumina forming the tubular parts (1) are between 0.02 mm and 0.1 mm.

5. Implant according to any one of claims 1 to 4, characterized in that the tubular portion (1) is encased at least partially with silicone or other appropriate plastic.

6. Implant according to any one of claims 1 to 5, characterized in that at the tubular portion (1) a plate (6) is applied which can contain one or more eyelets (7) for fixation by stitching.

7. Implant according to one or more of claims 1 to 6, characterized in that at least parts of the implant are made from biocompatible material, for example silicone or other appropriate plastics, from stainless steel, from titanium, from a noble metal such as silver, gold or platinum, or from a biological material.

8. Implant according to any one of claims 1 to 7, characterized in that at least parts of the implant are coated with suitable material to produce a desired biological reaction or to prevent an undesired biological reaction.

9. Implant according to any one of claims 1 to 8, characterized in that a check valve is provided in the tubular portion (1), by which retrograde flow of blood into the front eye chamber is prevented.